

a2 9. (amended) A method of introducing a recombinant expression cassette into a barley plant, the method comprising introducing a Ds element comprising the expression cassette into the plant; and selecting the plant with the expression cassette integrated into its genome.

REMARKS

1. Status of the claims

Claims 1-16 are currently under examination. Claims 1 and 9 are amended and claims 17-23 are withdrawn from consideration by the Examiner.

Claim 1 has been amended to recite a barley plant containing a transposon integrated into its genome. This amendment adds no new matter and is supported throughout the application and claims as-filed.

Claim 9 has been amended to recite selecting a plant with the expression cassette integrated into its genome. This amendment adds no new matter and is supported by the specification, *e.g.*, on page 18, line 33 through page 19, line 8.

Applicants thank the Examiner for acknowledging that claims 1-8 will be examined, in full, as they were originally drafted.

For convenience, the rejections will be addressed in the order presented in the Office Action.

2. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-8 were rejected as allegedly lacking adequate description to convey that applicants had possession of the claimed invention at the time the application was filed. The rejection alleges that the specification does not set forth the specific structural or physical feature that defines the claimed transgenic plants and concludes that the identity of transgenic barley and wheat plants in which Ac and/or Ds transposable elements are genomically integrated is uncertain because the structural and physical features of the claimed plants cannot be ascertained in the absence of information about the transferred nucleic acid sequence. Applicants respectfully traverse the rejection. The claims do refer to a structural and physical feature of the transgenic plants, *i.e.*, they must contain an Ac or Ds element integrated into the genome. As explained below, the designations "Ac" and "Ds" are not simply functional descriptors, but provide information about the

structural identity of these elements. Accordingly, the claims are fully compliant with the written description requirement.

"Ac and "Ds" provide information concerning the structural identity of the elements

The Examiner quotes the Federal Circuit in the *University of California v. Eli Lilly and Co.* 43 USPQ 2d 1398 (Fed. Cir. 1997) in support of the rejection, stating that

[t]he name cDNA...conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structure or physical characteristics; in other words, it thus does not describe human insulin cDNA.

Applicants submit that the rejection misapplies the Federal Circuit's holdings in *Lilly*. In *Lilly*, there was no information in the specification that related to the actual sequence of the claimed human insulin cDNA. Accordingly, no physical or structural characteristics of the claimed cDNA was provided. The Court concluded that "naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material." (*Lilly* at page 1399, emphasis added). In that context, the "human insulin cDNA" designation recited in the claims was found to refer to a function and not convey information about the identity of the molecule. In contrast, the name "Ac element" (or "Ds element") recited in the instant claims *does* convey information concerning the identity of the element. Not only does the application provide examples of Ac and Ds elements, but as indicated in the specification (*see, e.g.*, page 6, lines 21-22), maize Ac and Ds elements have been extensively characterized as far as both sequence and function is concerned. Accordingly, there is knowledge as to what that material consists of. Thus, the designations "Ac element" or "Ds element" do not merely reflect functions, but also refer to physical structures well known in the art, and as such, convey information about the elements.

"Ac element" and "Ds element" need not be described in detail

As discussed above and as evidenced by the many studies employing the Ac/Ds system (*see, e.g.*, references cited at page 3 of the specification), Ac and Ds elements are well known in the art. The written description requirement does not demand a detailed description of that which is known to one of ordinary skill in the art. The Revised Written Description Examination Guidelines, Federal Register, Vol. 66, No.4, 1099, Jan. 5, 2001, indicate that

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. (page 1106)

Example 16 of the Revised Interim Written Description Guidelines Training Materials specifically addresses an analogous situation. Example 16 describes the analysis of a claim that recites an antibody that is capable of binding to a particular antigen. In that Example, the specification contemplates, but does not teach in an example antibodies that bind to the antigen. The analysis indicates that, because antibodies are structurally well-defined and the production of antibodies is well-known, the disclosure meets the written description requirement. Similarly, Ac and Ds elements are structurally well-defined and can readily be prepared by one of skill. Accordingly, the disclosure in the specification meets the written description requirement. Applicants therefore respectfully request withdrawal of the rejection.

3. *Rejection under 35 U.S.C. § 102*

Claims 9, 11, and 12 were rejected as allegedly anticipated by McElroy *et al.* The claims have been amended to recite a step of selecting the plant with the expression cassette integrated into its genome. McElroy *et al.* describes integration of an Ac transposase gene into barley callus lines, but does not teach integration into a barley plant, nor does the reference teach selection of such a plant. Accordingly McElroy *et al.* does not anticipate the claims. Applicants therefore respectfully request withdrawal of the rejection.

4. *Rejection under 35 U.S.C. § 103*

Claims 1-4 were rejected as allegedly obvious over McElroy *et al.* in view of Wan *et al.* and Bancroft *et al.* The rejection alleges that because Wan *et al.* demonstrated successful transformation of barley and regeneration of transgenic barley plants, it would have been *prima facie* obvious to combine the method of barley regeneration as taught by Wan *et al.* with the method of introducing Ac and Ds elements into barley taught by McElroy *et al.*, especially given the success of Bancroft *et al.* in producing transgenic *Arabidopsis* containing integrated Ac and Ds elements. Such a combination would allegedly be made for the purpose of producing transgenic barley containing

integrated Ac and Ds elements. Further, the Examiner alleges that this would be the case without any surprising or unexplained results. Applicants traverse.

In order to establish a *prima facie* case of obviousness, the rejection must demonstrate that: (1) there is some suggestion or motivation to modify the reference or combine the reference teachings; (2) there is a reasonable expectation of success; and (3) the prior art references suggest all the claim elements. *See, e.g.*, MPEP § 2143; *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). The rejection has not established that these teachings could be combined with a reasonable expectation of success at arriving at the claimed invention. Moreover, based on the prior art, there was no motivation for one of skill to combine the references.

The claims at issue are drawn to transgenic barley plants containing an integrated Ac and/or Ds elements and methods of producing such plants. As noted by the Examiner, McElroy *et al.* does not teach a barley plant containing an integrated Ac or Ds element. Bancroft *et al.* is directed to *Arabidopsis*, not barley, and Wan *et al.* is directed to a completely different transformation system. No evidence or reasoning is provided in the rejection to indicate why one of skill could reasonably predict success in using the Ac/Ds system in barley to generate a plant with one or more of the elements integrated into the genome. Indeed, as discussed below, the prior art teaches away from applying an Ac/Ds transposon system to barley.

Izawa *et al.* (reference "AL" on the IDS submitted February 2, 2000) describe the use of the maize Ac/Ds system in a heterologous monocot, rice. These studies showed significant problems in the stability of the system for use as a stable transformation system for gene tagging and gene delivery. Frequent excision of Ds elements occurred in the F1 generation (*see, e.g.*, page 22, first column, first full paragraph; page 222, second column, first full paragraph). Furthermore, no linkage of Ds to mutant phenotypes in plants subjected to mutant screening was observed. This suggests that the high level of Ds activity, *i.e.*, excision, is too frequent to use for gene tagging to identify mutations associated with particular mutant phenotypes. Moreover, the frequent excision events observed in the F1 generation also indicated that Ds-mediated gene delivery of an expression cassette was not suitable for generating a stably transformed rice plant. Accordingly, Izawa *et al.* teach away from the successful implementation of the maize Ac/Ds system for gene transfer and tagging in heterologous monocots.

Although the Ac/Ds system was useful for gene delivery/tagging in dicots, in the only monocot in which it had been tested at the time of the invention, rice, the Ds element was too active.

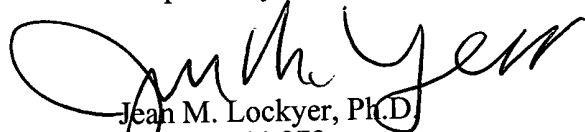
Therefore, there was no motivation to apply the system to other monocots to generate stable transformants, let alone expect that it would work. Barley, like rice, is a monocot. Accordingly, one of skill would not have been motivated to pursue Ac/Ds-mediated gene delivery and tagging in barley. Thus, the claims are nonobvious over the prior art. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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APPENDIX A
MARKED UP VERSION OF CLAIM AMENDMENTS

1. (amended) A barley plant containing a transposon integrated into its genome, wherein the transposon is selected from the group consisting of a Ds element and an Ac element[, and wherein the plant is selected from the group consisting of barley and wheat].

9. (amended) A method of introducing a recombinant expression cassette into a barley plant, the method comprising introducing a Ds element comprising the expression cassette into the plant[, wherein the plant is selected from the group consisting of barley and wheat]; and selecting the plant with the expression cassette integrated into its genome.